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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,932	11/22/2005	Peter Kufer	DEBE:059US/10505528	8324

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EXAMINER	
BAUGHMAN, MOLLY E	

ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,932	KUFER ET AL.	
	Examiner	Art Unit	
	Molly E. Baughman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2007 and 22 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 19-33* is/are pending in the application.

4a) Of the above claim(s) *1* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-33* is/are rejected.

7)☒ Claim(s) *24-26 and 29-33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments to claims 19 and 27, and cancellation of claim 34, in the reply filed on 8/27/2007 are acknowledged.

2. Applicant's correction of SEQ ID NO: 35, and submission of an updated sequencing listing, in the reply filed on 1/22/2008 is acknowledged.

3. Applicant's arguments filed 8/27/2007, with respect to claims 24-26 and 29-34 objections, have been fully considered but they are not found persuasive. These claims still contain non-elected subject matter, particularly, non-elected sequences. It is suggested that the applicant amend the claims to cancel such subject matter from the claims in order to overcome the objection.

4. Applicant's arguments, see pg. 8-9, filed 8/27/2007, with respect to the rejection(s) of claim(s) 22, 23, and 28 under 35 USC § 112, second paragraph, have been fully considered, but are not persuasive. Applicant's argued that the claims are no longer indefinite because the subject matter therein is defined by hybridization of the at least one cDNA-primer to transcripts of the functional genes of MAGE subfamilies... First, the amendment of claim 19 raises new issues under 35 USC § 112, second paragraph, as a composition comprising at least one suitable "cDNA-primer hybridizing to at least two different MAGE gene transcripts," is confusing as written. See further explanations and suggestions regarding the amendment below under "New Rejections necessitated by Amendment." Second, the amended language still is an intended use of the primers, as the claim is drawn to a product and the primer *hybridizing* (or capable of hybridizing) is still an intended use. While functional limitations of a product are taken

into consideration during examination, the primer as a composition (i.e. product) possesses characteristics as a sequence that are inherent to the primer and patentability cannot rely on the intended use of the primer (what method is it used for or what it is intended to anneal to). See MPEP 2112.01.

5. Applicant's arguments, see pg. 8-9, filed 8/27/2007, with respect to the rejection(s) of claim(s) 34 under 35 USC § 112, second paragraph, have been fully considered, and are persuasive since the claim has been cancelled.

6. Applicant's arguments, see pg. 9, filed 8/27/2007, with respect to rejection(s) of claim(s) 19, 22-23, and 27-28 under 35 USC § 102(b) (Sninsky et al., US 5,386,022) have been fully considered and are persuasive. Although the claims still possess issues under 35 USC § 112, second paragraph, claim 19 can be interpreted as intending to require the primers *being capable of* hybridizing to at least two different MAGE gene transcripts (see further explanation under "New Rejections necessitated by Amendment"), and therefore, the rejection has been withdrawn.

7. Applicant's arguments, see pg. 9-17, filed 8/27/2007, with respect to the following rejection(s):

a. Claims 19, 22-23 and 27-28 rejected under 35 U.S.C. 102(b) as being anticipated by Hoon et al. (US 6,057,105).

b. Claims 19, 22-23 and 27-28 rejected under 35 U.S.C. 102(e) as being anticipated by Kirken et al. (US 2006/0051324).

c. Claims 20-21, and 24 rejected under 35 U.S.C. 103(a) as being unpatentable over Kirken et al. (US 2006/0051324).

d. Claims 25-26 rejected under 35 U.S.C. 103(a) as being unpatentable over Kirken et al. (US 2006/0051324) as applied to claims 20-21, and 24 above, and further in view of Scanlan et al. (US 6,686,147) and Buck et al., "Design Strategies and Performance of Custom DNA Sequencing Primers," Biotechniques, Sept. 1999, Vol.27, No.3, pp. 528-536.

e. Claims 31-32 rejected under 35 U.S.C. 103(a) as being unpatentable over Hoon et al., as applied to claims 19, 22-23 and 27-28 above, and further in view of Gellerfors et al. (US 6,537,777) and Sagner et al. (US 6,691,041).

f. Claims 31-32 rejected under 35 U.S.C. 103(a) as being unpatentable over Kirken et al., as applied to claims 19, 22-23 and 27-28 above, and further in view of Gellerfors et al. (US 6,537,777) and Sagner et al. (US 6,691,041).

g. Claims 33-34 rejected under 35 U.S.C. 103(a) as being unpatentable over Hoon et al., as applied to claims 19, 22-23 and 27-28 above, and further in view of Boon-Falleur et al. (US 6,221,593 B1) and Buck et al., "Design Strategies and Performance of Custom DNA Sequencing Primers," Biotechniques, Sept. 1999, Vol.27, No.3, pp. 528-536.

h. Claims 33-34 rejected under 35 U.S.C. 103(a) as being unpatentable over Kirken et al., as applied to claims 19, 22-23 and 27-28 above, and further in view of Boon-Falleur et al. (US 6,221,593 B1) and Buck et al., "Design Strategies and Performance of Custom DNA Sequencing Primers," Biotechniques, Sept. 1999, Vol.27, No.3, pp. 528-536.

have been fully considered but are not found persuasive. Applicant's arguments over the above rejections are all centered on the fact that the primary references in each of the rejections have a different use of the sequence (i.e. primers) than the instant invention. Specifically, applicants argued that in the primary references, the sequences are PCR primers for amplification in a PCR reaction, and not cDNA primers for reverse transcription in a cDNA synthesis reaction. This is not found persuasive because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure *is capable of performing the intended use*, then it meets the claim (see MPEP 2112.01). In further explanation, the MPEP states that "a composition [in this case a primer] and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)." Therefore, the primers of each of the primary references above, are capable of hybridizing to at least two different MAGE gene transcripts for simultaneous reverse transcription of at least two different MAGE gene transcripts in a single cDNA-synthesis reaction, or in the case of the calibrator primers, are capable of hybridizing to an appropriate calibrator mRNA for reverse transcription of an appropriate calibrator mRNA.

8. Upon further consideration, new grounds of rejection have been made over claims 29-30 in light of the sequence correction of SEQ ID NO:35. Since Gellerfors et

al. (US 6,537,777) teach sequences (i.e. SEQ ID NO:7 and 10) which also comprise SEQ ID NO:35 (i.e. along with SEQ ID NO:44, 49, and 50, as stated in the previous Office Action), these claims will now be included in the rejection under 35 U.S.C. 103(a) as being unpatentable over Kirken et al., as applied to claims 19, 22-23 and 27-28 above, and further in view of Gellerfors et al. (US 6,537,777) and Sagner et al. (US 6,691,041). See below for full rejection.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 19-20, and 22-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 19-20, and 22-33 are confusing because it cannot be determined what is encompassed by "...cDNA-primer hybridizing to at least two different MAGE gene transcripts..." in claim 19. The phrase is confusing as written and it is not consistent with the nature of the claim (i.e. a product). It is suggested to amend the claim to a phrase such as, "...cDNA-primer *capable of* hybridizing to at least two different MAGE gene transcripts..."

b. Claims 27-32 are confusing because it cannot be determined what is encompassed by "...cDNA-primer hybridizing to an appropriate mRNA..." in

claim 27. The phrase is confusing as written and it is not consistent with the nature of the claim (i.e. a product). It is suggested to amend the claim to a phrase such as, "...cDNA-primer *capable of* hybridizing to an appropriate calibrator mRNA..."

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirken et al., as applied to claims 19, 22-23 and 27-28 in the previous Office Action under 35 U.S.C. 102(e), and further in view of Gellerfors et al. (US 6,537,777) and Sagner et al. (US 6,691,041).

The teachings of Kirken et al. can be found in the previous Office Action. Although Kirken teaches cDNA primers used during the same reaction to amplify calibrator mRNA (i.e. GAPDH (page 11[0144], and Table 2), he does not discuss PCR primers to PBGD according to SEQ ID NO: 35, 44, 49, and 50.

Gellerfors et al. teaches various sequences of human porphobilinogen deaminase (PBGD), one of which comprises the instant SEQ ID NOs: 35, 44, 49, and 50 (i.e. SEQ ID NO:10, col.7 and 73-74), and another which also comprises SEQ ID NO:35 (i.e. SEQ ID NO:7). Gellerfors et al. also teach primers (Iso379, 382, 375 and 376) designed to amplify the PBGD gene (col.11, 13 and Table 1).

One of ordinary skill in the art would have been motivated modify the diagnostic composition of Kirken et al. to include primers with sequences of SEQ ID NO: 44, 49, and 50, targeting the PBGD gene instead of GAPDH because Gellefors et al. show that the PBGD gene was well-known in the art and demonstrate that it was conventional in the art to design primers for a PCR reaction targeting the same PBGD sequence comprising the instant primer sequences, SEQ ID NO: 35, 44, 49, and 50. Furthermore, Sagner et al. state that there is a need for a more efficient and reliable quantification of nucleic acids during PCR reactions which are error-prone and demonstrate that the use of primers targeting a reference nucleic acid during amplification reactions of target DNA provides an efficiency-corrected quantification of nucleic acids (col.1-2, and 6). In example 1, Sagner demonstrate using primers targeting the PBGD gene in parallel of the target gene (CK20) during amplification, and further include a probe which hybridizes to a sequence of the PBGD gene (SEQ ID NO:7) which has the exact same

sequence as the instant SEQ ID NO:44, plus one nucleotide on the 5' end and two nucleotides on the 3' end (col.13 and 17). Therefore, the skilled artisan would have had a reasonable expectation of success in making similar primers to those of Gellefors and Sagner et al., targeting the PBGD gene, and include it in the diagnostic composition of Kirken et al., instead of GAPDH, for efficiency-corrected quantification of the target (MAGE) during PCR. It would have been obvious to one of ordinary skill in the art at the time of the invention to make a diagnostic composition and include primers with sequences consisting of SEQ ID NO: 35, 44, 49, and 50, which detect a sequence of the PBGD gene.

Summary

14. No claims are free of the prior art.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Molly E. Baughman whose telephone number is (571)272-4434. The examiner can normally be reached on Monday-Friday 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

/Molly E Baughman/
Examiner, Art Unit 1637